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**UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS**

**IN RE: NEW ENGLAND COMPOUNDING  
PHARMACY, INC. PRODUCTS LIABILITY  
LITIGATION**

MDL No. 1:13-md-02419-FDS

**THIS DOCUMENT RELATES TO:**

*Marko v. New England Compounding Pharmacy, Inc., et al., Docket No. 13-cv-10404;*  
*Pennington v. New England Compounding Pharmacy, Inc., et al., Docket No. 13-cv-10406;*  
*Leaverton v. New England Compounding Pharmacy, Inc., et al., Docket No. 13-cv-10408;*  
*Tolotti v. New England Compounding Pharmacy, Inc., et al., Docket No. 13-cv-10413;*  
*Zavacki v. New England Compounding Pharmacy, Inc., et al., Docket No. 13-cv-10441;*  
*Letizia New England Compounding Pharmacy, Inc., et al., Docket No. 13-cv-10442;*  
*Tisa v. New England Compounding Pharmacy, Inc., et al., Docket No. 13-cv-10446; and*  
*Devilli v. New England Compounding Pharmacy, Inc., et al., Docket No. 13-cv-11167*  
*Effendian v. New England Compounding Pharmacy, Inc., et al., Docket No. 13-cv-11233*  
*Guzman v. New England Compounding Pharmacy, Inc., et al., Docket No. 12-cv-12208*

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**LEGAL BRIEF ON IN SUPPORT OF DEFENDANTS, PREMIER ORTHOPAEDIC and  
SPORTS MEDICINE ASSOCIATES OF SOUTHERN NEW JERSEY, LLC, trading as  
PREMIER ORTHOPAEDIC ASSOCIATES, PREMIER ORTHOPAEDIC ASSOCIATES  
SURGICAL CENTER, LLC, and KIMBERLEY YVETTE SMITH, M.D. a/k/a KIMBERLEY  
YVETTE SMITH-MARTIN, M.D.'s MOTION TO DISMISS PURSUANT TO F.R.C.P. 12(b)(6)**

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### Introduction

As the Court is likely aware this case involves allegations against various entities wherein the plaintiffs claim that as a result of their negligence many patients were subject to epidural steroid injections, which later proved to be tainted with fungus. As a result many patients became ill, others had no symptoms and many patients brought suit against New England Compounding Pharmacy (Hereinafter "NECP"), the manufacturer of the injected medication. Also plaintiffs brought suit against the clinics and hospitals that purchased the medication to be injected into their patients.

NECP manufactured preservative free Methylprednisolone (hereinafter "MPA") and marketed that drug as being safe, clean, and effective for patients. Preservative free MPA has the added benefit to patients of causing less irritation to the spinal canal when injected as preservatives can often be an irritant when injected in the epidural space, causing pain and discomfort. Pain clinics, hospitals and surgery centers including the moving party Premier Orthopedic Associates, Premier Orthopedic Surgery Center and Dr. Yvette Smith-Martin (hereinafter the "Premier Defendants" or "Premier") bought MPA from NECP after representations were made to them that the drug was safe, effective and clean.

Unbeknownst to Premier this medication was being manufactured by NECP in laboratories which proved to be contaminated and dirty. (See Master Complaint filed by PSC dated 11/05/13 at dkt. No.545). As a result of NECP's actions, many patients were injected with MPA, which was contaminated with fungus. These patients filed suit and those cases were consolidated before this Honorable Court.

A master complaint was filed by the Plaintiff Steering Committee (hereinafter "PSC"). That complaint was adopted by several of the plaintiffs in this matter and in particular ten (10) plaintiffs' adopted the claims in the master complaint by way of short form complaints against the Premier Defendants.

The Premier defendants now move to dismiss plaintiff's claims according to F.R.C.P. 12(b)(6) for failing to state a claim upon which relief can be granted.

#### **STANDARD OF REVIEW**

Rule 12(b)(6) of the Federal Rules of Civil Procedure governs motions to dismiss for failure to state a claim upon which relief can be granted. Upon a motion to dismissed based on this rule, the Court must assume the truth of all well-pled facts and give the plaintiff the benefit of all reasonable inferences. Rando v. CVS Pharmacy, Inc, No. 12-11130-FDS, 2013

WL 6489947, at \*2 (D. Mass. Dec 9, 2013). To survive a motion to dismiss a complaint must contain sufficient factual matter, accepted as true, to "state a claim o relief that is plausible on its face." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed. 2d 929 (2007).

A peading that merely offers "labels and conclusions" or a "formulaic recitation of the elements of a cause of action" is insufficient. Id at 555, 127 S. Ct. 1995. U.S. v. Blackstone Med., Inc, 694 F. Supp. 2d 48, 61 (D. Mass. 2010).

Legal Argument

**I. Plaintiffs' claims for Negligence and Failure to Warn must be dismissed as a matter of law.**

***i. The Plaintiff's claims of negligence including plaintiffs' claims alleging failure to warn are subsumed by the New Jersey Product Liability Act.***

Plaintiff pled at Count VIII that the moving defendants failed to warn their patients that they were "being administered an unsafe, unreasonably dangerous drug compounded by NECC rather than a high quality drug produced by an FDA regulated Manufacturer." (See Master Complaint at para. 301). The plaintiffs also include a count for ordinary negligence at Count III of the complaint. Paragraph 234 of the master complaint alleges in essence that Premier failed to ensure that NECP would produce a safe and effective drug. The counts for lack of informed consent and negligence allege harm due to and caused by the contaminated medication, MPA. Each of these causes of action sound in negligence and call upon the providers to act according to a reasonably accepted duty of care. See Generally Largey v. Rothman, 110 N.J. 204 (1988). In this particular case however the plaintiff is calling upon the moving defendants to ensure the production of a safe and uncontaminated drug.

The exclusive remedy for when an individual is harmed by a product is the New Jersey Product Liability Act, (Hereinafter "NJPLA") regardless of the legal theory supporting the case. As

a result the plaintiff's claims for negligence are subsumed by the New Jersey Product Liability Act. The moving defendants are not subject to the New Jersey Product Liability Act because they are not considered sellers of the medication. Therefore the claims under Para. VIII and III must be dismissed.

Under New Jersey law negligence is no longer viable as a separate claim for harm caused by a defective product. Port Authority of New York and New Jersey v. Arcadian Corp., 189 F.3d 305, 313(1999) citing Oquendo v. Bettcher Indus. Inc., 939 F.Supp. 357, 361 (D.N.J. 1996). In Port Authority of NJ and NY, Supra, the plaintiffs brought suit against a fertilizer manufacturer, which was used by terrorists to create the explosives in the first World Trade Center attack in 1993. Plaintiff brought their case against the defendant under a theory of negligence and product liability. However the Court ruled that, "Even though plaintiff alleges a negligence claim in Count I, this count is based solely on harm caused by defendants' allegedly defective products. It therefore falls within the New Jersey Product Liability Act (the NJPLA), N.J.S.A. 2A:53C-1 et seq., which is 'the sole basis of relief under New Jersey law available to consumers injured by a defective product.'" Citing Repola v. Morbark Indus., Inc., 934 F.2d 483, 492 (3d Cir. 1991).

The law is plain and clear. When a person is injured because of a defective product the exclusive remedy is through the New Jersey Product Liability Act. The plaintiff cannot recover anything through a negligence action that he/she would otherwise not first recover under a strict liability claim for defective product.

***ii. The Premier Defendants are not subject to the New Jersey Product Liability Act and therefore the claims against Premier must be dismissed.***

Moving defendants are not subject to the New Jersey Product Liability Act because they are not "sellers" as defined by the statute. Determining whether a defendant is to be considered a seller under the statute is properly determined as a matter of law by the Courts. In Agurto v. Guhr, 381 N.J.Super. 519, 887 A.2d 159 (A.D.2005) the Court addressed the threshold issues of whether the seller of glue-mixing machine was a "seller" under the Product Liability Act. Resolving that issue required a determination as to whether seller had a duty that resulted in his being subject to principles of strict liability. Agurto v. Guhr, 381 N.J.Super. 519, (App. Div. 2005).

The New Jersey Products Liability act expressly excludes providers of professional services as "sellers" under the act. See N.J.S.A. 2A:58C-8. The NJPLA states generally that the term "product seller" does not include "[a] provider of professional

services in any case in which the sale or use of a product is incidental to the transaction and the essence of the transaction is the furnishing of judgment."

Although decided prior to the passage of the NJPLA, the Court in Magrine v. Spector, 100 N.J.Super. 223, 241 (App.Div.1968), aff'd, 53 N.J. 259,(1969) decided that a dentist was not strictly liable for defective needle used to treat patient. For purposes of product liability law, a hospital cannot be held strictly liable for a latently defective product supplied to it by another for its use in rendering treatment. Snyder v. Mekhjian, 244 N.J. Super. 281, 292-93, (App. Div. 1990) aff'd, 125 N.J. 328, 593 A.2d 318 (1991).

In Snyder physicians who provided services to a patient and the hospital at which the services were rendered found themselves as defendants in a suit brought by an HIV positive patient who contracted the disease after receiving a tainted blood transfusion. Id. at 309. The plaintiff brought suit seeking relief under the NJPLA. The Court announced that "Little need be said respecting the inapplicability of strict liability to [the hospital defendants] and the physician." Id. at 313. The Court explained that the physicians are clearly exempt under the holding and rationale of Newmark v. Gimbel's Inc, 54 N.J. 585 (1969)(Holding that in our judgment, the nature



of the services, the utility of and the need for them, involving as they do, the health and even survival of many people, are so important to the general welfare as to outweigh in the policy scale any need for the imposition on dentists and doctors of the rules of strict liability in tort).

Similarly the Snyder Court ruled that the hospital defendants were not subject to the strict liability of the NJPLA and held that for the purposes of product liability law, a hospital cannot be held strictly liable for a latently defective product supplied to it by another for its use in rendering treatment. Snyder v. Mekhjian, 244 N.J. Super. 281 at 293 (App. Div. 1990) citing Johnson v. Mountainside Hosp., 239 N.J. Super. 312 (App. Div. 1990).

Similar to Snyder the moving defendants in this case are the providers of medical services and as such the use of MPA was incidental to the "transaction" (injection) in this case. Perfectly in line with the statute's purpose and intent Premier was essentially providing a service where defendants were exercising medical judgment and providing treatment to patients.

As a result the moving defendants did not "sell" the tainted product to the patient. Moving logically therefore, because the exclusive remedy for a patient injured by a product falls within the NJPLA Premier cannot be held liable under the

New Jersey Product Liability Act for acts of negligence or causes of action that find their foundation in negligence. Plaintiff's claims are rooted in negligence but as pled basically allege that premier was negligent in not ensuring a "safe" and "Clean" product. The Essence of the claim, therefore is rooted in the product. Therefore, the plaintiffs' claims for negligence and lack of informed consent must be dismissed.<sup>1</sup>

***II. All claims for Battery must be dismissed.***

Under New Jersey Law the doctrine of Battery and Informed Consent (discussed above) are mutually exclusive of each other, requiring proving different elements. Whitley-Woodford v. Jones, 253 N.J. Super. 7, 10-11, (N.J. Super. Ct. App. Div. 1992)

Informed consent is a negligence concept based upon the duty of a doctor to give his patient appropriate information so that the patient can make an informed decision about proceeding with a particular medical course of action. Largey v. Rothman, 110 N.J. 204, 540 A.2d 504 (1988). Damages are based upon an

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<sup>1</sup> Informed consent claims are in addition precluded from being pursued against Hospitals or Healthcare Groups. Carr v. Brezel, A-3628-04T2, 2006 WL 657380 (N.J. Super. Ct. App. Div. Mar. 16, 2006) Holding (We decline to extend Howard to the facts of this case, as urged by plaintiff. Informed consent, as outlined above, deals with a *physician's* failure to adequately disclose material information to a patient. Here, there was no physician-patient relationship between the hospital and plaintiff. Citing Bennett v. Surgidev Corp., 311 N.J. Super. 567, 710 A.2d 1023 (App. Div. 1998) (emphasis in original). Therefore, as it relates to Premier Orthopedics and Premier Surgical Center, two defendant Healthcare Groups, any claims for informed consent must be dismissed as a matter of law.

adverse result which would have been avoided if proper information had been given. "Damages are measured by comparing the condition plaintiff would have been in, had the defendants not been negligent, with plaintiff's impaired condition as a result of negligence." Gleitman v. Cosgrove, 49 N.J. 22, 28, (1967)

Battery, on the other hand, is an intentional tort. It occurs when a doctor does not obtain the consent of his patient to perform a particular operative procedure. It is an unauthorized invasion of the body. Deviation from a standard of care is not involved and expert testimony on this issue is not necessary. An operation undertaken without consent (battery), even if perfectly performed with good medical results, may entitle a plaintiff to at least nominal and even punitive damages. Perna v. Pirozzi, 92 N.J. 446, (1983); Skripek v. Bergamo, 200 N.J.Super. 620, (App.Div.1985), certif. denied, 102 N.J. 303, (1985).

A required element of proving and properly pleading a claim for battery is to allege an unconsented-to touching, in this case an injection. Plaintiff has failed to allege that the plaintiffs did not consent to the operation/injection. In fact the plaintiffs allege that the patient was "unaware of the substantial health risk inherent in the use of NECC Contaminated

Drugs and did not consent to the injection of contaminated drugs into their bodies." (See Master Complaint at para. 297). The plaintiff's claim that they did not know of the substantial health risks is one of informed consent. The plaintiffs admit at para. 302 of the master complaint that they were given consent forms to sign and did so agreeing to the procedure. Therefore, it is undisputed that the plaintiffs consented to the treatment procedure, therefore, Battery cannot be a viable cause of action.

***III. All claims for Civil Conspiracy Must be dismissed***

Plaintiff's claims for civil conspiracy fail to allege with any particularity an intention to agree or conspire to intentionally commit a wrongful act. Furthermore, the PSC has failed to allege that the purported civil conspiracy caused the MPA to be contaminated. The PSC alleges that a conspiracy was hatched to defraud the Massachusetts Board of Pharmacy and circumvent their requirements. The alleged fraud was not alleged to have been directed to the plaintiffs.

Under New Jersey law, "a civil conspiracy is a combination of two or more persons acting in concert to commit an unlawful act, or to commit a lawful act by unlawful means, the principal element of which is an agreement between the parties to inflict a wrong against or injury upon another, and an overt act that

results in damage." Banco Popular N. Am. v. Gandi, 184 N.J. 161, 177 (2005); see also Morgan v. Union County Bd. of Chosen Freeholders, 268 N.J. Super. 337, 364 (App.Div.1993), certif. denied, 135 N.J. 468 (1994). A party is liable if he or she understands the general objectives of the conspiracy, accepts them, and makes an implicit or explicit agreement to further those objectives. Banco Popular, supra, 184 N.J. at 177. "Most importantly, the gist of the claim is not the unlawful agreement, but the underlying wrong which, absent the conspiracy, would give a right of action." Id. at 177-78

It should be noted that the reported cases sustaining civil conspiracy claims are based on underlying intentional torts. Lewis v. Airco, Inc., A-3509-08T3, 2011 WL 2731880 (N.J. Super. Ct. App. Div. July 15, 2011) citing Bd. of Educ. of Asbury Park v. Hoek, 38 N.J. 213, 238-39 (1962) (upholding a verdict based on a civil conspiracy where there was evidence showing that the conspirators attempted to deceive the plaintiff to purposely avoid a public bidding statute); Middlesex Concrete Prods. & Excavating Corp. v. Carteret Indus. Ass'n, 37 N.J. 507, 516-17 (1962) (holding that a complaint alleging a civil conspiracy based on the conspirators malicious interference with plaintiff's contractual rights and business or economic relations with a municipality was sufficient to state a cause of

action); State, Dep't of Treasury, Div. of Inv. ex rel. McCormac v. Qwest Commc'ns Int'l Inc., 387 N.J.Super. 469, 485-86 (App.Div.2006) (reversing trial court's order dismissing complaint on civil conspiracy claim where plaintiff pled common law fraud as an underlying wrong).

Plaintiff has failed to plead with any specificity or even generality how Premier intentionally conspired with NECP and at the very least failed to allege what unlawful act was pursued, conspired about, or acted upon in this case.

The complaint alleges that the conspiracy "principally involved NECC's request that the clinic related defendants provide patient names for patients the clinic related defendants intended to provide with MPA or other pharmaceuticals." (Master complaint at para. 340). The complaint goes on to explain that patient names provided to NECP were used by NECP to defraud The Massachusetts Board of Pharmacy patient safety requirements. The complaint fails to allege an agreement between Premier and NECP in any particularity or any agreement between any clinic or hospital and NECP. For this reason, all claims for civil conspiracy fail to state a cause of action upon which relief can be granted and must be dismissed.

**IV. Plaintiffs' claims for Consumer Fraud must be dismissed in accordance with the New Jersey Consumer Fraud Act.**

The Premier Defendants are not subject to the New Jersey Consumer Fraud Act (hereinafter "The NJCFA") as plead by the plaintiffs in this case. As a matter of law and by design the legislature specifically excluded Healthcare Providers from those subject to the NJCFA. Therefore, because The Premier Defendants are Healthcare providers they are not subject to the NJCFA and all claims against the moving defendant alleging violations of the act must be dismissed.

The Courts have explained that the Act has consistently been interpreted not to apply to learned professionals and therefore any change must come from the legislature. Macedo v. Dello Russou, 178 N.J. 340 (2004) see also Hampton Hosp v. Brazen, 288 N.J. Super. 372 (App. Div. 1996).

In Macedo the plaintiff alleged *inter alia* that her physicians falsely represented that the doctors involved in her care were all fully licensed with no limitations on their licenses. The complaint did not allege a breach of the standard of care. The lower court dismissed the case But the Appellate Division reversed holding that there was the potential for a claim under the NJCFA. See Macedo v. Dello Russo, 359 N.J. Super. 781 (App. Div. 2003) rev'd, 178 N.J. 340 (NJ). However the Supreme Court affirmed the trial court's ruling explaining

that the Act does not apply to professionals and therefore the case had properly been dismissed. See Macedo v. Dello Russo, 178 N.J. 340 (2004).

As a result of the above analysis therefore, all claims alleging a violation of The Act must be dismissed as a matter of law.

**V. Plaintiffs' claims of agency must be dismissed as a matter of Law for failing to state a claim.**

***i. Premier Exercised Absolutely No Control Over NECP With Regard To The Means Of Completing The Work.***

At Count X of the Master complaint the plaintiff alleges that Premier was the agent of NECP when it contracted with them for the production of medication. Specifically the complaint states:

Para. 332 The clinic related defendants manifested assent for NECC to act as their agent and on their behalf when the Clinic Related Defendants contracted with NECC to procure compounded drugs from NECC to administer to their patients, including plaintiffs.

Para. 334 At all times relevant herein, NECC acted within the scope of its agency with the clinic related defendants. As set forth herein, NECC acted negligently and or exhibited gross negligence in the compounding of NECC contaminated drugs.

Para. 335 The Clinic related defendants controlled the procurement of the drugs from NECC to be sold and administered to their patients including the plaintiffs.

Para. 336 As a result, the Clinic Related Defendants are responsible for the negligence, gross negligence and wrongful conduct of NECC in compounding the contaminated drugs administered to Plaintiffs.



At the very best, NECP was a vendor from whom Premier ordered medications to be administered to patients. NECP maintained this type of relationship with many if not hundreds of entities across the country and now plaintiff wishes to argue that NECP was the agent and the clinics acted as principles responsible for their actions and inactions.

If a principal is to be bound by his subordinate there must first exist a master servant relationship grounded in the principal's control over the servant's actions. The Courts have defined control to include several variables including the type and method of payment, provision of equipment and ability to terminate among others. Premier Orthopedics did not control the provision of medical services provided by NECP. Therefore, NECP is clearly an independent contractor and not an agent of the moving defendant. The New Jersey Courts have addressed this issue in the context of physicians providing medical services as part of a larger group.

In Lowe v. Zarghami, 158 N.J. 606 (1999) the Court announced several factors for determining independent contractor status and analyzing agency in general. The control test was discussed and explained that it is grounded in the common law master-servant relationship. New Jersey Property-Liability Ins. Guar. Ass'n v. State, 195 N.J.Super. 4, 8, (App.Div.). Whenever the

employer controls both the nature of the work performed and the manner in which the work is completed there is a master/servant relationship. Erickson v. Schwiers Co., 108 N.J.L. 481, 483,(E. & A.1932).

The Court in Lowe stated:

The control test assesses four factors in determining a worker's status: (1) the degree of control exercised by the employer over the means of completing the work; (2) the source of the worker's compensation; (3) the source of the worker's equipment and resources; and (4) the employer's termination rights. Delbridge v. Office of the Public Defender, 238 N.J.Super. 288, 320-21, 569 A.2d 854 (Law Div.1989) aff'd 297 N.J.Super. 1, 687 A.2d 748 (App.Div.1993); New Jersey Property, supra, 195 N.J.Super. at 14, 477 A.2d 826. The greater the degree of control exercised by the employer, the more likely a worker will be considered an employee.

Lowe v. Zarghami, 158 N.J. 606, 615-16, (1999). Each of the four factors mentioned in Lowe support a finding that NECP is an independent contractor and not the agent of Premier.

Premier Orthopedics most importantly did not control the manner and means by which NECP performed its duties. While Premier could have terminated its relationship with NECP at any time, that does not define whether one asserted any control over the other. The manner and means by which NECP cleaned its laboratories and where NECP manufactured their medication was not in the control of Premier Orthopedics. Stating that Premier had an obligation to inspect the facility and cease ordering

from NECP is not to say that Premier had a duty to control the means by which the medication was assembled.

(1) ***The Source Of The Worker's Compensation.***

While it was Premier's obligation to pay NECP for their product it was entirely up to NECP to determine how to pay and otherwise compensate their employees.

(2) ***The Source Of The Worker's Equipment And Resources.***

There is no argument that Premier Orthopedic did not control the equipment and resources used to manufacture the medications in question. The plaintiffs allege that Premier could have inspected the equipment and resources used but there is no allegation that the equipment and resources were in control of the moving defendants. Certainly the decision to use certain equipment and where to use such equipment was exclusively in the hands of NECP only.

(3) ***The Employer's Termination Rights.***

As stated above Premier Orthopedic could have, at any time and for any reason stopped ordering medications from NECP. However, Premier could not terminate an individual employee of NECP or make decisions to stop processing drugs in the manner in which they did in this case.

The PSC has not pled any facts consistent with Premier exerting control over NECP in any form. As a result the pleadings fail to provide a basis upon which relief can be granted.

***ii. The Relative Nature Of The Work Test Is Not Applicable To This Matter But Would Not Create A Master Servant Relationship If Applied Regardless.***

The relative nature of the work test is not applicable and further does not deem Premier Orthopedics Associates vicariously liable for NECP's negligence.

In Lowe Supra the Court announced that where the control test is inconclusive, and there are questions of public policy implications at issue the relative nature of the work test may be considered to determine agency. Id. at 618. Overwhelmingly, the relative nature of the work test has been employed in various situations where the scope of social legislation may be contradicted. See Marcus v. Eastern Agricultural Ass'n, 32, M.J. 460 (1960) (Worker's compensation Act); Lowe Supra, 158 N.J. at 617, (Tort Claims Act), Stomel v. City of Camden, 192 N.J. 137, 153-56 (Employee status for purposes of C.E.P.A claim).

In Lowe the lower court ruled that the defendant doctor was an independent contractor working for the University of Medicine and Dentistry and thus obviating the need for plaintiff to serve a Tort Claims Notice. The plaintiff had failed to provide a

Tort Claim Notice to the defendant doctor and therefore was facing dismissal of his case. The Appellate Division reversed but could not rely completely on the control test in order to find the defendant an employee. Rather, the Court employed the more relaxed, "relative nature of the work" standard. This standard was expressly relied upon to uphold social legislation namely, the Tort Claims Act.

The relative nature of the work test looks at the extent of the economic dependence of the worker upon the business he serves and the relationship of the nature of his work to the operation of that business in order to determine, what under the totality of the circumstances the character of the relationship is. Lowe at 616. Nevertheless, control remains potential indicia of the status of the relationship under this test. Id.

NECP was not completely and independently reliant upon Premier Orthopedics as they contracted with many different clinics and hospitals. Furthermore and quite importantly Premier Orthopedics is not in the business of manufacturing medications. The nature of the work done by the two is not similar in any respect. While ordering medications from NECP furthers NECP's goals of making selling medication for a profit, nothing Premier does or does not do as part of its day to day operation created a dependence on the other.

Finally, the business of Premier Orthopedics is not one of pursuing some public policy goal or legislation as was the case in Lowe. In that respect NECP is more akin to a vendor. See Neal v. N.J. State Dept. of Corr., 366 N.J. Super. 570, 574 (App. Div. 2004)(Where defendant, a private corporation contracted with a prison to provide physicians for medical care was not responsible for its independent contractors actions and was more akin to a staffing agency).

As pled therefore, the plaintiff fails to make out a claim upon which relief can be granted. There are no facts or even suggestions that premier somehow controlled the process employed by NECP for manufacturing medications. Finally, the relative nature of NECP's business is not interrelated to or dependent upon Premier's operations. Therefore, plaintiff's claims for agency must be dismissed.

***iii. Premier Orthopedics Associates Cannot Be Held Vicariously Liable For The Actions Of Its Independent Contractor.***

Premier Orthopedics did not entrust their independent contractor with a non-delegable duty.

Where one engages the services of an independent contractor, that person is generally not liable for the latter's negligent acts. It is well established under New Jersey Law that a principal is generally not liable to the negligent acts of an

independent contractor. Majestic Realty Associates, Inc. v. Toti Contracting Co., 30 N.J. 425, 430-431 (1959). The rule is based upon the rationale that an independent contractor contracts to do certain work according to his own methods without being subject to the control of his employer except as to the product or result of his work." Pfenninger v. Hunterton Cent. Reg'l High School, 167 N.J. 230, 252 (2001). The Courts have applied an exception to this well settled area of the law, namely when a contractor is entrusted with a non-delegable duty. Marek v. Professional Health Services, Inc., 179 N.J. Super. 433 (App. Div. 1981).

In Marek, an employer arranged for Professional Health Services (PHS) to take chest x-rays, audiograms and pulmonary function tests of its employees. A PHS vice-president described his company as a "mobile health testing service". Marek v. Professional Health Services, Inc., 179 N.J. Super. 433, 435-36, (App. Div. 1981). PHS developed the x-rays taken at the mobile unit at plaintiff's employer's site and they were delivered to the independent-contractor doctor's office. The doctor was to read the x-rays and report positive findings only to PHS, thereafter they were relayed to the patient's employer. *Id.* at 439.

Ultimately, PHS was responsible for relaying the appropriate readings to the patient. The radiologist, Dr. Johnson negligently read the plaintiff's chest x-ray causing a delay in diagnosis and treatment of his cancer. The Court decided that even though the radiology defendant was an independent contractor the duty to provide the appropriate results to the patient was that of PHS. In other words, it was PHS's primary purpose to deliver care to the patients.

The Marek case has been used over and over again by plaintiff's attempting to bootstrap the healthcare groups with liability. However, the case at bar is distinguishable on all fronts. First, the plaintiff in the instant case fails to pled with any specificity that the manufacturing of medication was that of the hospitals and clinics. Without, at the very least, pleading that Premier was responsible for the manufacturing of and distribution of medications, one cannot argue that a non-delegable duty was assigned under the Marek decision.

***iv. The Principal, Premier Orthopedics Did Not Provide Apparent Authority For NECP.***

Clearly Premier Orthopedics is not responsible for the actions of NECP under a theory of apparent authority. In order to be held responsible for the actions of an independent contractor using the theory of apparent authority there must be some assertion or "holding out" of that contractor to the public



as if they are acting with the authority of the principal. Such is not the instance here.

In Cordero v. Christ Hospital, 403 N.J. Super. 306, (2008), the Appellate Division considered whether a hospital who contracted its anesthesia services out to an independent contractor was liable for the negligence of a physician member of the anesthesiology group. The Court held that "when a hospital provides a doctor for a patient and the totality of the circumstances created by the hospital's action and inaction would lead a patient to reasonably believe the doctor's care is rendered in behalf of the hospital, the hospital has held out that doctor as its agent." *Id.* at 103. In determining whether to hold the hospital liable for the negligence of the anesthesiologist, the Court noted that imputing liability upon a principal prevents a principal from "choosing to act through agents whom it has clothed with the trappings of authority and then determining at a later time whether the consequences of their acts offer an advantage." *Id.* at 104, 105 citing (Restatement (Third) of Agency § 2.03, comment c (2006)).

Clearly the patients were not "clothed with the trappings of authority" on behalf of Premier Orthopedics in this particular case. No such allegations find their way into the plaintiff's pleadings. Furthermore, there is no evidence that

the patient was under any presumption or impression that NECP was working for on or behalf of Premier Orthopedics Associates. Therefore, Premier cannot be held responsible for the acts or omissions of NECP based on the apparent authority theory.

**VI. Plaintiffs' claim for punitive damages must be dismissed as a matter of law.**

Claims for punitive damages are governed by New Jersey's Punitive Damages Act, N.J.S.A. 2A:15-5.9, *et seq.* [hereinafter "the PDA"]. The PDA specifies that no degree of negligence, not even gross negligence, is sufficient to establish a claim for punitive damages. Recklessness alone is insufficient; recklessness must be accompanied by deliberate action or inaction accompanied by knowledge of a high degree of probability of harm to the decedent. N.J.S.A. 2A:15-5.12.

Punitive damages may be awarded to the plaintiff only if the plaintiff proves, by clear and convincing evidence, that the harm suffered was the result of the defendant's acts or omissions, and such acts or omissions were actuated by actual malice or accompanied by a wanton and willful disregard of persons who foreseeably might be harmed by those acts or omissions. This burden of proof **may not be satisfied by proof of any degree of negligence including gross negligence.**

*Id.* (emphasis added).

The terminology is important and is defined by the statute. "Actual malice" is defined as "an intentional wrongdoing in the

sense of an evil-minded act. N.J.S.A. 2A:15-5.10. "Punitive damages" are "exemplary damages and means damages awarded against a party in a civil action because of aggravating circumstances in order to penalize and to provide additional deterrence against a defendant to discourage similar conduct in the future." *Id.* "Wanton and willful disregard" means "a deliberate act or omission with knowledge of a high degree of probability of harm to another and reckless indifference to the consequences of such act or omission." *Id.*

Punitive damages "are not to be applied in the ordinary unaggravated tort case." Berg v. Reaction Motors, 37 N.J. 396, 413 (1962). *See also Stern v Abramson*, 150 N.J. Super. 571, 573 (Law Div. 1977) (intentional tort must rise to the level of outrage to justify punitive damage award). A punitive damages claim cannot be supported by the same set of facts that supports the negligence claim, without more. Entwistle v. Draves, 102 N.J. 559 (1986); Edwards v. Our Lady of Lourdes Hosp., 217 N.J. Super. 448, 461 (App. Div. 1987). Punitive damages are assessed only when a wrongdoer's conduct is "especially egregious." Leimgruber v. Claridge Associates, Ltd., 73 N.J. 450, 454 (1977).

In the present case, plaintiff has asserted that The Premier Defendants acted recklessly in administering the patient

MPA from NECP. The PSC also states that the Premier Defendants acted in gross negligence when administering the MPA to its patients. While the plaintiff may have made a case of negligence they have not set forth sufficient facts to support a claim for punitive damages. Something more than gross negligence or regular negligence must be pled in order to support an award for punitive damages. There are no facts pled to support egregious, wanton and willful conduct. Plaintiff also falls short of alleging an intentional act on behalf of Premier. Therefore plaintiffs' claims for punitive damages must be dismissed.

**Conclusion**

The claims outlined above must be dismissed as a matter of law according to F.R.C.P. and the law as outlined above.

Respectfully Submitted,

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Blumberg & Wolk, LLC

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